

UNITED STATED DEPARTMENT OF COMMERCE Patent and Trad mark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS

Washington, D.C. 20231

FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. APPLICATION NO. 08/692.314 08/05/96 HAMLIN R 910458.CDA **EXAMINER** IM52/0810 JOHN J. GAGEL MAKI,S FISH & RICHARDSON, P.C. ART UNIT PAPER NUMBER 225 FRANKLIN STREET BOSTON K MA 02110-2804 1733 DATE MAILED: 08/10/99

Please find below and/or attached an Office communication concerning this application or proceeding.

. Commissioner of Patents and Trademarks





UNITED STATES DEARTMENT OF COMMERCE Patent and Track Park Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

			·
SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/692.314	1		

EXAMINER			
ART UNIT	PAPER NUMBER		
1733	56		

DATE MAILED:

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

The amendment filed on 7-29-99 canceling claims 119-121, 131-132, 137-139, 149-150 and 152-165 drawn to the "constructively elected invention" and amending independent claims 116 and 134 and dependent claims 118, 127, 136, 145 so that claims 116, 118, 122-125, 127-128, 133-134, 136, 140-143, 145-146, 151 and newly submitted claims 166-187 are readable on a non-elected invention; and presenting newly submitted claims 188-199 drawn to a non-elected invention is non-responsive (MPEP § 821.03). The remaining claims are not readable on the "constructively elected invention" because claims 116, 118, 122-125, 127-128, 133-134, 136, 140-143, 145-146, 151, and 166-199 are directed to a different species (hereinafter referred to as species #2) than that originally presented in the CPA filed 11-13-98 (hereinafter referred to as species #1). It is also noted that claims 188-199 are directed to a product (identified as Group II below) whereas the original claims in the CPA filed 11-13-98 are directed to a method (identified as Group I below).

Since the above-mentioned amendment appears to be a *bona fide* attempt to reply, applicant is given a TIME PERIOD of ONE (1) MONTH or THIRTY (30) DAYS, whichever is longer, from the mailing date of this notice within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD UNDER 37 CFR 1.136(a) ARE AVAILABLE.

With respect to "the constructively elected invention", the following comments are made: Newly submitted claims 188-199, amended independent claims 116 and 134 with their respective dependent claims 118, 122-125, 127-128, 133, 136, 140-143, 145-146, 151 and newly presented dependent claims 166-187 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The invention originally claimed in the CPA filed 11-13-98 is identified below as species #1 and the invention claimed in newly submitted claims 188-199, amended independent claims 116 and 134 with their respective dependent claims 118, 122-125, 127-128, 133, 136, 140-143, 145-146, 151 and newly presented claims 166-187 is identified below as species #2:

species #1 - method for making a coronary angioplasty catheter balloon comprising co-extruding a tube/parison having a first layer comprising a first polymeric material and a second layer comprising a second polymeric material wherein the first layer has a greater burst strength than the second layer and the first polymeric material comprises polyester (see for example original claims 118-121, 131-132, 136-139, 149-150 and 152-165 in the CPA filed 11-13-98).

species #2 - method for making an angioplasty catheter balloon comprising forming a tube/parison having an extruded first layer comprising a first polymeric material and an extruded second layer comprising a second polymeric material wherein the first polymeric material is selected from the group consisting of polyetheretherketone (PEK) and polyetherketone (PEK).

Art Unit 1733

Currently, no claim is generic (None of the newly submitted claims 188-199, amended independent claims 116 and 134 with their respective dependent claims 118, 122-125, 127-128, 133, 136, 140-143, 145-146, 151, and newly presented claims 166-187 in the amendment filed 7-29-99 are generic).

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

With respect to claims 188-199, the following is also noted: Newly submitted claims 188-199 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The originally claimed invention is identified below as Group I and the invention as claimed in newly submitted claims 188-199 is identified below as Group II:

- I. Originally presented claims 116, 118-125, 127-128, 130-134, 136-143, 145-146 and 148-165 in the CPA filed 11-13-98, drawn to a method of making a coronary angioplasty catheter balloon comprising co-extruding a tube/parison having a first layer comprising a first polymeric material and a second layer comprising a second polymeric material wherein the first layer has a greater burst strength than the second layer and the first polymeric material comprises polyester, classified in class 264, subclass 173.16.
- II. Claims 188-189, drawn to medical catheter balloon comprising a first extruded layer comprising a first polymeric material and a second extruded layer comprising a second polymeric material wherein the first polymeric material is selected from the group consisting of polyetheretherketone (PEK) and polyetherketone (PEK), classified in class 604, subclass 96.

The inventions are distinct, each from the other because:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process as claimed can be used to make other and materially different product such as a balloon which is not sized and configured for intravascular coronary angioplasty use or a balloon which has a burst strength which is not in excess of seven atmospheres. Alternatively, the product as claimed can be made by another and materially different process such as forming the layers by using injection molding instead of coextruding OR laminating preform layers instead of coextruding.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 116, 118, 122-125, 127-128, 133-134, 136, 140-143, 145-146, 151, and 166-199 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP §821.03.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven D. Maki whose telephone number is (703) 308-2068. The examiner can normally be reached on Monday to Friday from 7:00 AM to 3:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Ball, can be reached on (703) 308-2058. The fax phone number for Art Unit 1733 is (703) 305-7718. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0661.

Steven D. Maki August 10, 1999

STEVEN D. MAKI PRIMARY EXAMINER

> GROUP 1868 A ∪ 1733